UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)**
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' OMNIBUS MOTIONS IN LIMINE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rules, Statutes, & Regulations

MOTIONS

1. **Defendants' motion to preclude Plaintiffs from asking the jury to "send a message."**

Defendants' motion to preclude Plaintiffs from asking the jury to "send a message" is overbroad. Plaintiffs can and should be permitted to argue the bases for punitive damages consistent with applicable law, especially now that Defendants have decided not to bifurcate the trial for punitive damages. For instance, in New Jersey (and elsewhere), punitive damages can be awarded to punish a defendant's misconduct, and to deter similar misconduct in the future. *Fireman v. Armstrong World Indus., Inc.*, 908 F.2d 171, 196 (3d Cir. 1992). As many courts recognize, a plaintiff's asking the jury to "send a message" to deter future misconduct by a defendant is a permissible shorthand for allowable argument and evidence about punitive damages. *See, e.g.*, *Jones v. City of Chicago*, 14-cv-4023, 2017 WL 413613, at *5 (N.D. Ill. Jan. 31, 2017) (collecting cases); *see also, e.g.*, *Carr v. Cty. of San Diego*, 19-cv-1139, 2022 WL 2161513, at *7 (S.D. Cal. June 15, 2022) ("As to exhortations to 'send a message,' the Court agrees with Plaintiff that such argument is permissible when punitive damages are at issue, as here.").

Defendants' cited authority disproves their own assertions. Their lead case only granted a motion "insofar as it seek to block any variation of the Golden Rule argument." *Webb v. Cent. Fla. Inves., Inc.*, No. 18-cv-1304, 2021 WL 852139, at *1 (S.D. W. Va. Mar. 5, 2021). Here, Plaintiffs have stipulated they will not invoke

"the golden rule." *Webb* specifically stated it "will entertain permitting the deterrent-type argument" in a second trial phase on punitive damages, an option Defendants have chosen to forego here. *Id.* Similarly, another of Defendants' cases simply precluded the phrase "send a message" and nothing more. *Hassebrock v. Air & Liquid Sys. Corp.*, No. 14-1835, 2016 WL 4496917, at *8 (W.D. Wash. Apr. 11, 2016) ("Plaintiffs are free to focus on the punitive nature of the award consistent with the language of an appropriate punitive damages jury instruction.").

2. Defendants' motion regarding unrelated regulatory actions.

Plaintiffs agree that completely irrelevant regulatory actions should not be referenced. However, Defendants ask for overbroad relief, as they are focused on regulatory actions that are not irrelevant, because they relate to the valsartan products at issue, the facilities where the valsartan products were manufactured, and/or Defendants' overall deficient cGMP activities that establish the context within which the cGMP violations that caused the contamination occurred.

For example, Teva had many communications with the FDA about highly relevant issues, even if they were not laser-focused on the "specific manufacturing processes and chemical reactions" that resulted in NDMA or NDEA. For instance, Teva had numerous back-and-forth communications with the FDA about recall-related issues, even though these communications did not narrowly mention "specific manufacturing processes and chemical reactions." *See, e.g.*, TEVA-

MDL2875-00346079 (Pls.' Teva Ex. 1)[1] (7/16/2018 email from FDA Officer to Teva threatening that [redacted]").

Teva also unsuccessfully asked the FDA to let it sell products containing valsartan API from a non-party, Dr. Reddy's, because Teva argued (as it also argues here) that Teva's own testing suggested the API met specifications. Plaintiffs address this fully in their separate response to Teva's motions in limine, which Plaintiff incorporates by reference.

As a final example, the FDA issued a Warning Letter to a Teva facility in China in April 2017, stating that its API was adulterated because of cGMP deviations, including some that are very similar to those at ZHP's facility that led to the NDMA contamination. *See* Pls.' Teva Ex. 2. Again, this regulatory document does not specifically relate to the "specific manufacturing processes" for the at-issue valsartan API or finished dose, but certainly goes to Teva's notice and knowledge about the types of issues it should have been focused on (and was not) when it audited ZHP's valsartan API facility.

The Court previously ruled that evidence related to the products in question

[1] Plaintiffs' ZHP exhibits are attached to Adam M. Slater's certification in opposition to Defendants' motions in limine. Plaintiffs' Teva exhibits are attached to David Stanoch's certification in opposition to Defendants' motions in limine. Plaintiffs' Torrent exhibits are attached to Daniel Nigh's certification in opposition to Defendants' motions in limine.

and the facilities where the products were manufactured are absolutely relevant. *See* ECF 303 (11/25/19 Order).[2] That is because cGMP violations within the facility are directly relevant to a determination of whether any products manufactured in the facility were adulterated. *See generally* 21 C.F.R. Parts 210, 211. The July 18, 2017 Establishment Inspection Report (EIR) (TORRENT-MDL2875-00004362 (Pls.' Torrent Ex. 1)) to Torrent is relevant and admissible for this reason. The EIR and Form 483s examine cGMP compliance, including facility procedures and training protocols. (*Id.* at 1–4). While the application of protocols to specific products is also examined in EIRs and Form 483s, their scope is the facility as a whole. The 2017 EIR was "comprehensive." (*Id.* at 1). It is therefore relevant and highly probative as to the facility-wide policies, procedures, and practices applicable to the manufacture of Torrent's VCDs in 2017. This is even more telling given that the 2017 EIR was a follow up to a 2016 EIR in which action was indicated. *Id.* at 2.

Defendants also charge that the EIR and Form 483s are improper character evidence of Torrent's noncompliance with Torrent's cGMP. (Defs.' Br. 7) To the

[2] "6. Plaintiffs' request for foreign regulatory documents is GRANTED in part and DENIED in part. Plaintiffs' request for all foreign regulatory documents sent or received regarding Valsartan and the Valsartan recall is DENIED. However, for each relevant facility the defendants shall produce by December 31, 2019, all regulatory inspection reports, warning letters akin to what the FDA sends, 483-like documents, the responses to these documents, root cause analyses regarding the Valsartan contamination, and documents regarding potential or actual nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period."

contrary, the 2017 EIR and Form 483s, which are part of a string of regulatory actions against Torrent, (TORRENT-MDL2875-00004362, at 2 (Pls.' Torrent Ex. 1)), are admissible to, among other reasons, show notice of prohibited actions, and establish the "organization's routine practice … to prove that on a particular occasion the … organization acted in accordance with the habit or routine practice." Fed. R. Evid. 406. Moreover, the 2017 EIR and Form 483s go to the credibility of Torrent witnesses and to rebut claims that Torrent fully complied with cGMP or regularly "passed" inspections; Plaintiffs anticipate that Torrent, through its witnesses will make such representations. (*See* ECF 2571, at ¶¶ 25–28).

In addition, documents that demonstrate systemic cGMP deficits within the Defendants, which carried forth and manifested with the products in question, are also obviously relevant. For example, documents showing that a company was failing to properly investigate out of specification ("OOS") findings on product testing, and did not remedy that problem, then failed to properly investigate OOS findings for the valsartan products at issue, are relevant. This includes, for instance, Teva's awareness of quality-related issues at a different ZHP facility than the one that manufactured valsartan API. *See, e.g.*, TEVA-MDL2875-00399765 (Pls.' Teva Ex. 3) (Teva June 2015 audit report of ZHP's Xunqiao Linhai facility noting ZHP had identified [redacted]). Again, this report does not relate to the "specific

manufacturing process" for at-issue valsartan API or finished dose, but certainly informs as to Teva's firsthand knowledge and notice of ZHP's company-wide quality assurance and compliance problems, including one of the same problems (ignoring unknown peaks) underlying the nitrosamine issues in this case.

Finally, Defendants likely intend to assert that they were "good companies" that had no FDA issues in the past, so the valsartan failings were an anomaly. Plaintiffs have moved to exclude such arguments (Pls.' MIL 20); however to the extent those arguments are permitted, that would open the door to the full extent of all FDA communications about issues in the Defendants' operations, regardless of whether related to the valsartan or not. This includes, for instance, the Form 483s issued by the FDA to Teva's Malta facility in April 2014 and February 2017. *See* Defs.' Mem. at 5-6. This facility is directly relevant as a location where Teva made at-issue finished dose valsartan. That these Form 483s did not relate "to the specific manufacturing processes and reactions" for the at-issue valsartan API (nor would they, as finished dose, not API, was made at the Malta facility), does not mean they should be off limits if Defendants wrongly tout sterling regulatory track records.

3. Defendants' motion regarding litigation conduct and discovery disputes.

Defendants title and present their motion as if Plaintiffs intend to inject the history of the discovery in the litigation at trial. Plaintiffs agree that discovery issues in general should not be presented at trial. However, that does not encompass

material issues with key documents. For example, the Jinsheng Lin July 27, 2017 email was sent to eleven ZHP employees including important custodians/30(b)(6) witnesses Min Li, Peng Dong, Jucai Ge, and Linda Lin, yet was found in only Min Li's custodial file—as a PDF copied from his laptop on after Novartis confirmed that there was NDMA in the valsartan API. No other recipient had the email in their custodial file—**including the author of the email Jinsheng Lin**, and no other recipient was listed as a duplicate custodian. (Pls.' ZHP Ex. 47). When confronted with the email, Linda Lin, the head of the ZHP Regulatory Affairs department, said [redacted]. (Linda Lin 5/4/2021 Dep. Tr. 84:17-85:4 (Pls.' ZHP Ex. 1)). Another example is Jinsheng Lin's custodial file, which is materially deficient. To begin with, the July 27, 2017 email authored by Jinsheng Lin is NOT included in his custodial file, and nor is he listed as a duplicate custodian on the only version of that document produced—the pdf copy found in Min Li's custodial file. The earliest document with actual metadata is dated December 7, 2017, despite Jinsheng Lin having worked at ZHP since July 2012. There is one document without a metadata date before December 7. 2017, and that is three pages from a CEMAT lab notebook in Chinese, dated July 24, 2017 on the bottom of the pages.

This is not a discovery issue, it is evidence of incomplete files of key players, and shines light on the context around this devastating smoking gun email, and the

jury should know this in evaluating Plaintiffs' claims, especially for fraud and punitive damages, which Defendants have decided not to bifurcate. Similarly, the refusal of Baohua Chen to appear for a Court ordered deposition, which remains the subject of a pending motion, should be disclosed to the jury so they will know the evidence available to Plaintiffs did not include his sworn deposition testimony—otherwise, the jury may speculate that his testimony was not helpful to Plaintiffs.

None of these examples are routine discovery matters. The jury should know that the full files for key players were not available, and that the Chairman of ZHP refused to appear for his Court-ordered deposition. These are relevant facts. *Hammons v. Ethicon, Inc.*, 190 A.3d 1248, 1283 (Pa. Super. Ct. 2018) (holding: "The evidence of document destruction in this case was highly relevant…."), *aff'd*, 240 A.3d 537 (Pa. 2020); *Hrymoc v. Ethicon, Inc.*, No. A-1083-18, 2021 WL 836854, at *38 (N.J. App. Div. Mar. 2, 2021) (holding: "The spoliation evidence presented in Hrymoc was sufficiently relevant to be admitted…."), *aff'd as modified on unrelated issues*, 297 A.3d 1245 (N.J. 2023).

4. Defendants' motion related to references to the cancer related terms that accurately describe the contaminating impurities NDMA and NDEA.

Defendants desperately ask the Court to sanitize the trial and play down the concrete fact that NDMA and NDEA are genotoxic, mutagenic, probable human carcinogens. That is perhaps the central fact in this trial since it was the contamination with these substances that presented the safety risk that required the

recalls and is the basis for the economic damages at issue. As ZHP stated in its press releases announcing the recall, the contamination created "an unacceptable **carcinogenic risk** to the intended patient population." (SOLCO00024231 (Pls.' ZHP Ex. 2); SOLCO00024226 (Pls.' ZHP Ex. 3)). This cannot be disputed because it is set in stone. For example:

- "N-nitrosiethylamine should be regarded for practical purposes as if it were carcinogenic to humans," and "N-nitrosodimethylamine should be regarded for practical purposes as if it were carcinogenic to humans." IARC, *Some N-Nitroso Compounds*, p. 107, 152 (1978) (Pls.' ZHP Ex. 4); *see also* IARC, *Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Volumes 1 to 42*, p. 42 (1987) (clarifying that NDMA and NDEA are probable human carcinogens) (Pls.' ZHP Ex. 5).

- "Some structural groups were identified to be of such high potency that intakes even below the TTC would be associated with a high probability of a significant carcinogenic risk (Cheeseman et al. 1999, Kroes et al. 2004). This group of high potency genotoxic carcinogens comprises aflatoxin-like-, N-nitroso-, and azoxy-compounds that have to be excluded from the TTC approach." EMEA, *Guideline on the Limits of Genotoxic Impurities*, p. 6 (2006) (Pls.' ZHP Ex. 6).

- FDA, *Guidance for Industry: Genotoxic and Carcinogenic Impurities in Drug Substances and Products* (2008) ("[T]here are some compounds containing certain structural groups (aflatoxin-like-, N-nitroso-, and azoxy-structures) that have extremely high carcinogenic potency and are excluded from the threshold approach.") (Pls.' ZHP Ex. 7).

- "Based upon laboratory studies in which tumors have been induced in all species examined at relatively low doses, NDMA is clearly carcinogenic. There is overwhelming evidence that NDMA is mutagenic and clastogenic." "Qualitatively, the metabolism of NDMA appears to be similar in humans and animals; as a result, it is considered highly likely that NDMA is carcinogenic to humans, potentially at relatively low levels of exposure." "NDMA is a genotoxic carcinogen and exposure should be reduced to the extent possible." *World Health Organization, N-Nitrosodimethylamine* (2002) (Torrent Ex. 2)

ZHP's 30(b)(6) witnesses have repeatedly agreed: NDMA is "a **highly toxic impurity**… I agree that NDMA is a genotoxic impurity" (Jucai Ge 5/27/22 Dep. Tr., 159:12-161:20, 173:13-14 (Pls.' ZHP Ex. 8); [redacted] (Eric Gu 4/6/2021 Dep. Tr. 66:15-16 (Pls.' ZHP Ex. 9); Min Li 4/20/2021 Dep. Tr., 101:22-102:8 ("NDMA and NDEA are considered to be mutagenic/genotoxic impurities") (Pls.' ZHP Ex. 10); Jun Du 5/27/21 Dep. Tr., 96:2-3 [redacted] (Pls.' ZHP Ex. 11); Hai Wang 3/10/21 Dep. Tr., 276:5-11, 321:16-22 (confirming that NDMA [redacted]) (Pls.' ZHP Ex. 12)). Teva and Torrent's witnesses testified similarly. *See, e.g.*, (Nudelman 4/8/21 Dep. at 170:18-20 (Pls.' Teva Ex. 4) [redacted]); *id.* at 82:12-83:4 [redacted] TORRENT-MDL2875-00190373: Torrent's Health Hazard Evaluation of Amlodipine/Valsartan/Hydrochlorothiazide [redacted]) (Pls.' Torrent Ex. 2); Jocelyn Rivera 2/22/2021 Dep. Tr. 35:24-36:5 (when discussing the statement from the WHO document, [redacted] (Pls.' Torrent Ex. 3); Sushil Jaiswal 6/4/2021 Dep. Tr. 63:2-6 (confirming [redacted]

[redacted]) (Pls.' Torrent Ex. 4); Sushil Jaiswal 6/4/2021 Dep. Tr. 63:2-6 ([redacted]) (Pls.' Torrent Ex. 4).

In the face of these immutable and central facts, Defendants present a general argument counting the number of times the terms were used during days and days of depositions focused on the import of the contamination of valsartan with the genotoxic, mutagenic, probable human carcinogens NDMA and NDEA. Of course, not one example of an "excessive" use of these terms is presented. By necessity, these terms—which define the risk that led to the recalls—will be central to the trial.

5. Defendants' motion regarding the "reptile theory."

This motion, which attempts to micromanage Plaintiffs in an unreasonably restrictive way is easily denied. Seen for what it is, Defendants actually present the descriptions of what happened here, and the reason for the recalls, as improper arguments. It is a fact that Defendants manufactured and sold the contaminated drugs as approved, safe, and of the required quality. Defendants' misrepresentations as to what was contained in the pills, and failure to comply with cGMPs and other regulatory requirements meant to protect the safety of their widely used products is a fact. Defendants cannot stop Plaintiffs from explaining what happened and the consequences.

More generally, this is a motion that is filed and rejected in pharmaceutical

cases. A simple Westlaw search of "reptile theory" reveals two cases in the entire Third Circuit. The motions were denied in both cases. *R.D. v. Shohola*, No. 3:16-CV-01056, 2019 WL 6134726, at *1, 4 (M.D. Pa. Nov. 19, 2019); *Botey v. Green*, 3:12-CV-1520, 2017 WL 2485231, at *2 (M.D. Pa. June 8, 2017). In *Shohola*, the court was clear, even in response to a more specific motion:

> At the outset, in motion in limine in Number 15, (Doc. 317), Shohola invites us to preclude reference to (1) camp "safety rules," (2) the "safety" of the community or the public at large, (3) the "safety" of the jurors themselves, and (4) potential harms or "dangers" that could theoretically be caused by Shohola's conduct. **We will decline this invitation at this time but invite the parties to raise objections to specific evidence as the trial progresses. At the outset, recognizing the inclusionary nature of the rules of relevance we find that evidence regarding safety rules and practices may be relevant to the questions of negligence that lie at the heart of this case. We note that we are not alone in this view. Quite the contrary, the potential relevance of such matters has long been recognized by this court.** *Kube v. Bethlehem Steel Corp.*, 390 F.2d 506, 507 (3d Cir. 1968); *Christner v. E. W. Bliss Co.*, 524 F. Supp. 1122, 1126 (M.D. Pa. 1981).

2019 WL 6134726, at *4.[3] This Court should deny Defendants' even more generic

[3] Even Defendants' own case is circumspect about what can be excluded as improper "reptile theory" arguments:

> The Court does not interpret Defendant's motion in limine as seeking to exclude testimony from Plaintiffs' counsel or witnesses that the product was not safe for use by the coal miners. The ultimate question for the jury in this matter is whether the location of the operator handle on the Caterpillar RB220 Roof Bolter rendered it a defective and unreasonably dangerous piece of equipment. As a result, whether the product was safe for use by coal miners in the performance of their job is relevant to this question. Thus, it is entirely appropriate for Plaintiffs' counsel to contend at trial that the product was not safe.

motion for the same reasons. *See also S.J. v. Albany Unified Sch. Dist.*, No. 20-CV-06414-KAW, 2023 WL 4930837, at *1 (N.D. Cal. Aug. 1, 2023) (denying a "reptile theory" motion and explaining: "Defendant's motion in limine is premature and overbroad; there is no indication that Plaintiff will make improper arguments, and simply referring to the larger community or a duty to prevent harm would not be improper."); *Uzhca v. Wal-Mart*, No. 17 Civ. 3850, 2023 WL 2529186, at *6 (S.D.N.Y. Mar. 15, 2023) ("A district court is entitled to give attorneys wide latitude in formulating their arguments, and this Court declines to set a categorical ban on any trial tactics, either reptilian or with respect to the general safety standard.").

Finally, the trial claims are also based on consumer protection laws that

---

Brooks v. Caterpillar Glob. Mining Am., LLC, No. 4:14CV-00022-JHM, 2017 WL 3401476, at *9 (W.D. Ky. Aug. 8, 2017). Defendants' then misleadingly quote the court's recitation of the defendants' argument in *Elkins v. Automatic Data Processing, Inc.*, No. EDCV 21-606 JGB KKx, 2023 WL 7354621, at *7 (C.D. Cal. Apr. 19, 2023), as if it were the court's ruling. Additionally, the plaintiff in that case appears to have largely agreed to the defendants' motion, and the Court provided no analysis or reasoning as a result. Defendants again misleadingly quote the defendant's argument from *Lee v. Dennison*, No. 2:19-cv-01332-KJD-NJK, 2023 WL 221339, at *1-2 (D. Nev. Jan. 17, 2023). That court made no ruling that the plaintiffs could not discuss "safety." And the plaintiffs seemed to acquiesce to the motion as simply "baseless pre-trial speculation." *Id.* at *1. The court consequently agreed and wrote the following platitudes: "The Court reminds the parties that arguments should be made consistent with the jury instructions and according to the standard of care. And as Plaintiff argued, the Defendants may object to specific instances of misconduct as may or may not occur during the trial." *Id.* Defendants' reliance on a series of unpublished cases, which they then had to misconstrue and misleadingly quote, in support of their motion to preclude arguments from a 2009 book unconnected to this case, shows how baseless and misguided the motion is.

include elements such as the conduct being contrary to public policy or affecting the public interest. *See, e.g.*, *Reichert v. Keefe Commissary Network, L.L.C.*, 332 F.R.D. 541, 553 (W.D. Wash. 2019) (element of Washington CPL is that the practice "impacts the public interest"); *Bassett v. Credit Bureau Servs., Inc.*, 554 F. Supp. 3d 1000, 1018 (D. Neb. 2021) (element of Nebraska CPL is that the practice impact the "public interest" and that plaintiff should show "widespread effects" or "public policy" implications to prove element); *Champion Pro Consulting Grp. v. Impact Sports Football*, 845 F.3d 104, 109 (4th Cir. 2016) (discussing North Carolina CPL and that unfairness can be established regarding a defendant's practice "if it offends established public policy"). This is yet another reason to deny this motion.

6. Defendants' motion regarding their misrepresentations to the FDA.

Defendants made materially false representations to the FDA that enabled the contaminated drugs to be sold. For example, in filing the DMF amendment for the zinc chloride process on December 10, 2013, ZHP misrepresented that the process change was minor, (PRINSTON00073104 (Ex. 13)), defined as "[c]hanges in the drug substance, drug product, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product," 21 C.F.R. 314.70(d)(1), when it had been internally classified as "critical"/"major," which is defined as [redacted]

[redacted] (ZHP01843067 (Pls.' ZHP Ex. 14); ZHP00469149 (Pls.' ZHP Ex. 15)). And more important, the DMF falsely represented that the process change did not result in the creation of n-nitroso compounds and listed the impurities—failing to disclose the presence of NDMA and NDEA. (HUAHAI-US00007898-7899 (stating that "there is not any high potency genotoxic group, such as, aflatoxin-like-, N-nitroso-, and azoxy-compound has been included in these impurities.") (Pls.' ZHP Ex. 16); PRINSTON00080118-80119 (same) (Pls.' ZHP Ex. 17). Then, after learning on or before July 27, 2017, that there was NDMA in the valsartan API, that this was due to the quenching with sodium nitrite, and this was a common problem with the manufacture of sartans, ZHP continued to interact with the FDA as if its valsartan API met the specifications and was not contaminated with prohibited genotoxic carcinogens. (ZHP00190573, with translations (Pls.' ZHP Exs. 18-19, 49)). Defendants cannot keep these facts from the jury, especially if they intend to rely on FDA statements made without knowledge of the full facts.

Similarly, Teva violated its own SOPs in failing to promptly inform the FDA about a potential genotoxic substance in Teva's finished dose valsartan. Plaintiffs address this fully in their response to Teva's motions in limine (ECF 2644).

Teva also did not disclose in communications with the FDA in 2014 about

ZHP's manufacturing change that (i) internally, Teva classified the change as "major," but told the FDA it was "minor to moderate," and (ii) did not disclose the results of any of Teva's own testing of the API (because there were none). *See, e.g.*, TEVA-MDL2875-00279311 (Pls.' Teva Ex. 5) ([redacted]); TEVA-MDL2875-00001886 (Pls.' Teva Ex. 6) (Teva letter to FDA classifying same change as [redacted]

None of this implicates *Buckman Co. v. Pls.' Legal Committee*, 531 U.S. 341 (2001), because preemption under that case only applies where the Plaintiffs' sole theory of recovery is that the defendant defrauded the FDA. In *Buckman*, the Court did not review, let alone dismiss, all of the plaintiffs' claims. Instead, it only considered the district court's decision to dismiss the "'fraud-on-the-FDA' claims, first on the ground that they were expressly pre-empted by the MDA, and then, after our decision in *Medtronic*[*, Inc. v. Lohr*, 518 U.S. 470 (1996)], **on the ground that these claims amounted to an improper assertion of a private right of action under the MDA**." *Buckman*, 531 U.S. at 347 (emphasis added). The *Buckman* Court was clear about how its decision conformed with the holding in *Medtronic, Inc. v. Lohr*, 518 U.S. at 492-93, 501, that federal law does not preempt actual state law claims:

> Notwithstanding the fact that *Medtronic* did not squarely address the question of implied pre-emption, it is clear that

> the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, **not solely from the violation of FDCA requirements**. *See* 518 U.S., at 481, 116 S.Ct. 2240. **In the present case, however, the fraud claims exist *solely* by virtue of the FDCA disclosure requirements.**

Buckman, 531 U.S. at 352-53 (emphasis added); *see also McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040-41 (9th Cir. 2015) (stating "[t]he appellees would have us conclude that any use of federal law to establish a standard of care is an attempt to enforce the underlying federal provisions, but **we do not accept that proposition**," and explaining "*Buckman* recognized that *Lohr*, while dealing explicitly with only express preemption, left the door open to state-law claims 'parallel' to federal requirements" (emphasis added)). Here, plaintiffs' claims are for breach of express warranty, violation of consumer protection statutes, and fraud on the payors, all under state law. Defendants' misrepresentations to the FDA and regarding their FDA compliance are simply facts that are part of the proofs, not the sole claim or sole basis for any claim. Thus, Defendants' misleading of the FDA is fair game.

7. Defendants' motion to preclude experts from commenting on corporate intent, motive, or ethics.

This motion mixes concepts in an effort to sweep facts and key corporate admissions under the umbrella of experts speculating as to why Defendants did what they did. As with most of their motions, Defendants cite general legal propositions and fail to actually present an example that would be inadmissible.

Plaintiffs agree that their experts will not speculate in a vacuum. However, that does not include Defendants' factual statements as to their motives in taking the ill-fated steps they did. For example, Jun Du admitted to the FDA investigator that the change to the zinc chloride process was intended to reduce the cost and increase the yield of the valsartan API, which is what allowed ZHP to "dominate the world market share." (PRINSTON00162373 (Pls.' ZHP Ex. 20)). Similarly, a Torrent internal document confirmed that Torrent purchased API from ZHP for one important profit driven reason: because it was [redacted] TORRENT-MDL2875-00005763 (Pls.' Torrent Ex. 5).

Teva, for instance, internally considered price to be the only factor for valsartan API. *See, e.g.*, TEVA-MDL2875-00108342 ("[redacted] (Pls.' Teva Ex. 7). As to Torrent, this Court already refused to preclude the opinions of Plaintiffs' cGMP expert Philip Russ (*see* ECF 2581 at 25-26) about Torrent's internally-documented business decision to seek out a sole-source valsartan API supplier such as ZHP to reduce costs. *See, e.g.*, TORRENT-MDL2875-00436416 (Pls.' Torrent Ex. 6). Torrent itself described the valsartan API it was purchasing from ZHP to be [redacted] TORRENTMDL2875-00005763 (Pls.' Torrent Ex. 5).

None of these facts are improper arguments or interpretations about corporate motives of state mind. These are facts created by Defendants themselves. They

cannot prevent Plaintiffs' experts from explaining their significance.

Regarding ethics, Min Li testified as a 30(b)(6) witness that, *in his own words*, it would be unethical to perform a study where humans would deliberately be given NDMA, due to the cancer risk, and it would have been unethical to "knowingly" sell the valsartan contaminated with NDMA—which is exactly what ZHP did beginning no later than July 27, 2017. (Min Li. 4/22/21 Dep. Tr., 685:11-687:4, 696:3-697:4; 699:24-700:15 (Pls.' ZHP Ex. 21)). This was ZHP's own testimony.

These and similar statements and admissions by Defendants can be presented to experts to explain their import and significance if Plaintiffs so choose.

8. Defendants' motion regarding foreign regulatory statements and actions.

Defendants mischaracterize and deliberately obscure the facts and the context, again providing generic legal cites without linking them to the facts in this case, on this record. Here, foreign regulatory statements and actions were explicitly applied and or known—thus providing notice, and are an integral part of the story here. This was recognized by Judge Schneider in the ruling cited by Defendants. *See* ECF 303.[4]

[4] "6. Plaintiffs' request for foreign regulatory documents is GRANTED in part and DENIED in part. Plaintiffs' request for all foreign regulatory documents sent or received regarding Valsartan and the Valsartan recall is DENIED. However, for each relevant facility the defendants shall produce by December 31, 2019, all regulatory inspection reports, warning letters akin to what the FDA sends, 483-like documents, the responses to these documents, root cause analyses regarding the Valsartan contamination, and documents regarding potential or actual nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

For example, ZHP admitted that it referenced and relied on the EMA Guideline on the Limits of Genotoxic Impurities, and the EMA Questions and Answers on the implementation of the Guideline, in performing the risk assessment for impurities at the time of the process changes, and this EMA Guideline was referenced in ZHP's DMFs for both manufacturing processes. (Peng Dong, 4/1/21 Dep. Tr., 369:22-370:9, 377:7-378:7, 378:17-379:20, 385:4-16 (Pls.' ZHP Ex. 22); HUAHAI-US00007898-7899 (Pls.' ZHP Ex. 16); PRINSTON00080118-80119 (Pls.' ZHP Ex. 17)). In addition to actually applying this Guidance and citing to it in a submission to the FDA, the contents also demonstrate important information that served as notice of the importance of identifying and controlling genotoxic impurities. For example, Peng Dong provided the following characteristically indirect testimony on the issue:

> Was ZHP aware in 2011 that N-nitroso compounds were structures to be of very high concern according to the European Medicines Agency? Yes or no.
>
> A. Your question is not a simple answer that I can simply answer with a yes or no. **In 2011, ZHP conducted corresponding work based on the knowledge of the authorities**, the industry, and ZHP valsartan zinc chloride process at that time. **The authorities also included EDQM.**

7. Plaintiffs' request for foreign sales, marketing materials and agreements is DENIED. However, to the extent defendants have possession, custody, or control of documents from any source regarding unknown and unidentified testing peaks or general toxic impurities in Valsartan API or Valsartan, the documents shall be produced."

(Peng Dong 4/1/2021 Dep. Tr. 391:16-392:3 (emphasis added) (Pls.' ZHP Ex. 22)).

Another example of probative evidence from a foreign regulatory agency is Health Canada's evaluation and testing of the RLD, brand Diovan, demonstrating that it did not contain NDMA or NDEA. (Pls.' ZHP Ex. 23). This example may not be needed, if Plaintiffs' MIL regarding Valisure is granted, and Defendants are precluded from asserting that there was NDMA or NDEA or other nitrosamines in the RLDs—since there is zero evidence to support such an assertion.

Similarly, the EMA and EDQM's final inspection report regarding their September 10-13, 2018 inspection of ZHP is highly probative of ZHP's cGMP violations in this case. The report explicitly discusses and applies ICH Q7, ICH Q8, ICH Q9, ICH Q10, and ICH Q11, (ZHP01862673, 1862679-682, 1862685, 1862687, 1862689-90, 1862692, 1862695-96, 1862708, 1862711, 1862713 (Pls.' ZHP Ex. 24)), which are international guidelines that ZHP has admitted governed its actions here and that it attempted to comply with at all times. (*See, e.g.*, Peng Dong 3/29/2021 Dep. Tr. 33:20-34:10 (stating, "For API products, including valsartan API, we would confirm the quality specifications per the requirements of ICH.") (Pls.' ZHP Ex. 25); *id.* at 35:22-24 ("We conducted our work based on the requirements of ICH as well as the regulations of our internal SOPs."); *id.* at 36:15-19, 37:5-9, 40:9-11, 55:16-18, 56:22-57:2, 60:24-61:4, 62:13-16, 86:3-4, 86:11-13, 86:21-24, 105:17-19, 107:6-10). To be clear, the inspection report is a damning

assessment of ZHP's conduct:

> As part of the root cause analysis of the NDMA/NDEA contamination, the development of the 2011/2012 revised valsartan manufacturing process (introduction of the ZnCl2 process) was reviewed and the following observations were made:
>
> a. The modified process was developed by the Huahai Pharmaceuticals R&D facility 'Shanghai SynCores Technologies Inc.'. **Contrary to what the company stated in their retrospective analysis of the process change, the core principles of ICH Q8, Q9 and Q10 were not considered and potential impurity profiles and associated risks were not addressed by the R&D laboratory**;
>
> b. Furthermore, **no risk assessment was made by the company to identify the impurities related to the new solvent used (DMF) when implementing the process proposed by R&D**.
>
> EU GMP Part II no. 2.21, 12.11; ICH Q9, ICH Q10 no. 3.2, ICH Q11 no. 3.1.4

(ZHP01862679-80 (emphasis added) (Pls.' ZHP Ex. 24)). And ZHP 30(b)(6) witness Eric Gu agreed that ZHP failed to properly apply ICH Q8, Q9, and Q10. (Eric Gu 4/5/2021 Dep. Tr. 244:22-245:23 (Pls.' ZHP Ex. 48)). ZHP's admissions as to the import of these standards and reliance on the European guidance is fatal to this motion.

Defendants also fail to tell the Court about the interaction of the foreign regulatory scheme with the FDA. In order to monitor overseas manufacturing, the FDA participates in a cost-sharing program with foreign governments (including Australia, Canada, Switzerland, Austria, the UK, Germany, Sweden, Denmark,

Japan, Singapore, and Italy[5]) known as the Pharmaceutical Inspection Co-operation Scheme ("PIC/S").[6] Regulators in these countries work together to inspect facilities pursuant to shared standards and have regularly scheduled meetings to discuss their shared views on compliance with cGMPs. (*See* FDACDER_0001171-77 (documenting a December 2015 PIC/S Meeting regarding data integrity guidelines to be used by industry, drafted in conjunction with officials at the FDA and officials from other foreign regulatory offices) (obtained by Plaintiffs pursuant to a FOIA request) (Pls.' ZHP Ex. 27)). Logically, it makes no difference whether the inspector who visited an overseas site was from Australia, Japan, the United Kingdom, Italy, or the United States—the inspector would still have observed the manufacturing processes at issue and would be documenting their observations about Defendants' compliance (or non-compliance) based upon the same cGMP standards each and every regulatory inspector for PIC/S countries assents to follow. Indeed, inspectors from the PIC/S participating countries attend group trainings, on issues such as how to inspect for data integrity issues with workshops providing practical examples on how to inspect, which further demonstrates their shared understanding of cGMP compliance. (FDACDER_0001187-89 (Obtained pursuant to Plaintiffs' FOIA

[5] Italy was the lead inspector for the September 10-13, 2018 inspection of ZHP.
[6] *See* "List of Participating PIC/S Countries," https://www.picscheme.org/en/members (ZHP Ex. 26).

Requests) (Pls.' ZHP Ex. 28)).[7] Taking Defendants' position regarding foreign regulatory inspection reports (and communications related to those inspections) to its logical end would mean that two documents could detail similar cGMP violations which occur at the same valsartan manufacturing facility in two different years, but because one of those documents was authored by an Italian inspector, Plaintiffs could not present it to the jury. Defendants' motion is not based on any attempt to shield the jury from more stringent foreign standards. It is simply meant to cut Plaintiffs off from evidence directly related to their claims.

For example, this played out in Defendants' own contemporaneous documents and analyses in the wake of the recalls. Teva, for example, prepared a "Global Quality Report" analyzing the nitrosamines in valsartan API from ZHP. *See* TEVA-MDL2875-00693423 (Pls.' Teva Ex. 8). Teva deliberately sought to avoid testing finished dose batches of valsartan in the US market, and instead tested batches in Europe and cited European or EMA references in testing this product. *Id.* However, Teva concluded, based on these tests, that NDMA would be in every finished dose valsartan pill that contained API from ZHP, wherever sold. *Id.* Indeed, Teva cited this and other arguably "European" regulatory references in its official

[7] That the foreign regulatory inspectors follow the same guidelines and principals regarding cGMPs completely undercuts Defendants' argument that foreign regulatory documents are not relevant to the extent that the standards between the countries are different. With respect to inspections and documentation regarding compliance with cGMPs, the standards are universal and consistent.

response to the FDA about Teva's finished dose sold in the United States.

Foreign regulatory entities also inspected the same facilities that made valsartan API or finished dose. These factual observations squarely fall within Magistrate Judge Schneider's ruling about foreign discovery.

Because foreign regulatory statements or actions is so closely intertwined with the facts and background of the underlying nitrosamine issues, the Court should deny Defendants' motion. Defendants' own authority supports a contextual analysis, at worst. *See, e.g.*, *In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 181 F. Supp. 3d 278, 307 (E.D. Pa. 2016) (denying motion in limine to exclude foreign regulatory actions or materials because "[t]he context and content of the evidence regarding foreign labels and foreign regulatory actions will be important to my determining its probative value and any risk of prejudice, undue delay, or confusion to the jury.").

9. Defendants' motion regarding the absence of cross-claims and the subject of indemnification.

Plaintiffs do not intend to inform the jury that Defendants did not file cross-claims against one-another, or to discuss indemnification between Defendants. None of that should be mentioned. Plaintiffs' MIL regarding the absence of cross-claims, and the subject of indemnification, is intended to preclude Defendants from making arguments that blame or assert the fault of one another because they have asserted no cross-claims for indemnification or contribution, have not alleged that

the others did anything wrong in their Answers, and have no experts to point the finger at one another.

[redacted]

[8] The letters may be relevant to the pre-suit notice issue the Court is addressing on the dispositive motions, and the redactions can be revisited in that event.

[redacted]

10. Defendants' motion regarding individual consumers' cancer diagnoses and economic losses.

Plaintiffs will not be presenting evidence as to any individual's cancer diagnosis, or any individual consumer's economic losses. Plaintiffs agree with Defendants that, "***First*, any evidence of VCD users who developed cancer has no relevance to his case. This trial does not involve any personal injury claims by patients who took defendants' VCDs. Rather, the plaintiffs are third-party payors seeking economic loss damages. That certain individuals took VCDs and subsequently developed cancer is irrelevant to the TPP Plaintiffs' claims."** (Defs.' Br. 21-22). This is why Plaintiffs filed an MIL to confirm that general causation and general causation concepts should not be injected into the trial.

Just as Plaintiffs should not put in evidence that people developed cancer, Defendants cannot insert evidence or argument that people did not develop cancer—or could not develop cancer. The same reasoning underpinning this motion from Defendants also underlies Plaintiffs' motion. Just as specific causation of a person's cancer is irrelevant, so too is general causation of cancer. Defendants cannot have it both ways. Just as Defendants state that they would need to put in evidence to

refute an assertion of specific causation by Plaintiffs, Plaintiffs would need to put in evidence to refute a denial of general causation by Defendants.

This trial is not about causation of cancer. The trial is about unacceptable carcinogenic risk eviscerating the value of a contaminated drug—an issue that has already been conclusively established by the recalls and Defendants' across the board admissions that the contamination rendered the API and pills unsaleable.

Similarly, no individual consumer's economic loss will be presented. However, Plaintiffs may present the facts of consumer transactions to demonstrate how the process works—initiating the financial transaction at issue at the cash register. To the extent the Assignors' insureds communicated about the recalls and mentioned cancer, that would be a factual matter about how events unfolded.

Furthermore, Defendants have indicated they intend to argue that unspecified individuals or entities were "superseding/intervening causes." If Defendants argue that physicians (the only category identified) were "superseding/intervening causes" of TPP subclass trial members' economic injuries—and Plaintiffs have filed a motion in limine to preclude this—then Plaintiffs must be able to present evidence to counter that argument.

12. Defendants' motion regarding valsartan sold outside the United States, and regarding API suppliers other than ZHP.

At the outset, it is important to point out that Defendants misrepresent the sweep of Judge Schneider's Order. Judge Schneider recognized the relevance of the

products sold in the United States, and the activities in the facilities where the products were manufactured—including to the extent those products were not sold to be incorporated into finished dose for sale in the United States. *See* ECF 303.

The motion is presented with broad terminology, but the text actually focuses on two discrete points related only to Teva, and should be denied on both points.

By way of background, Teva purchased valsartan API from multiple firms during the relevant time period, including trial defendant ZHP; non-trial defendant Mylan; non-parties such as Dr. Reddy's Laboratories and Jubilant Pharma; and Teva even made its own valsartan API at its India facility. Defendants' motion does not mention any of these non-ZHP valsartan API suppliers besides Mylan, so Plaintiffs respond here as to Mylan API only.

Plaintiffs do not intend to try and prove Teva's liability for valsartan API that Teva sourced from Mylan. The revelations about Mylan's valsartan API stretch from August 2018 to November 2018, when Teva finally (and belatedly) recalled finished dose valsartan containing Mylan's API.

What is relevant at the upcoming trial, and may be implicated, is this: [redacted]

[redacted] *See, e.g.*, TEVA-MDL2875-00549885 (Pls.' Teva Ex. 9).

[redacted] What is more, Defendants already specifically tried to preclude Plaintiffs' cGMP expert, Philip Russ, from opining about this discrete issue. The Court denied Defendants' motion in its entirety as to Mr. Russ. *See* ECF 2581 at 25-26. Teva's instant motion in limine is simply an attempt to get at second bite at the apple. The Court should not countenance this.

Also, in any event, the lengthy parade of horribles posited by Teva (*see* Defs.' Br. 26) is baseless. Succinct evidence and argument about the narrow matter of Teva's decision to belatedly implement a hold on all valsartan, then to lift it very quickly thereafter without any testing, will not "dramatically expand the scope of trial." (Defs.' Br. 26).

As to Teva's assertions about valsartan sold outside the United States, it is unclear what exactly Teva seeks to preclude. Plaintiffs do not seek damages for valsartan sales outside the United States, and do not intend to focus on such sales. Teva misquotes Magistrate Judge Schneider's ruling on foreign sales. While

wholesale discovery of foreign sales was denied, he specifically permitted discovery of "documents from any source regarding unknown and unidentified testing peaks or generic toxic impurities in Valsartan or Valsartan." ECF 303 at ¶ 7.

Every example of foreign sales that Teva cites (Defs.' Br. 27-28) falls within the scope of the permissible foreign discovery allowed by Magistrate Judge Schneider. [redacted] (*see* TEVA-MDL2875-00514869 (Pls.' Teva Ex. 10)) [redacted], falls exactly within the scope of Magistrate Judge Schneider's order. Moreover, this document is illustrative of both Teva's capabilities to analyze unknown peaks, and processes for same (which were not followed for valsartan). Teva's vague reference to its "testing capabilities worldwide" (Defs.' Br. 28) is too indefinite to support a sweeping evidentiary exclusion at trial. But it suffices to say here that evidence concerning Teva's testing capabilities *as to valsartan* is very probative in this trial. By way of example only, Teva has argued that it lacked the capabilities to perform gas chromatography testing of ZHP's valsartan API, or was unaware of the need or ability for such testing. [redacted] *See* TEVA-MDL2875-00734327 (Pls.' Teva Ex. 11).

This motion does not reference ZHP's sales of API to entities outside the United States; thus, that is not at issue. However, to be sure, this motion cannot encompass ZHP's sales of API to Novartis in Europe—which Novartis thoroughly tested, discovering the NDMA and then forcing ZHP to disclose the contamination to the world. (ZHP00310309-10 (Pls.' ZHP Ex. 31); ZHP00380568 (Pls.' ZHP Ex. 32); ZHP01390017 (Pls.' ZHP Ex. 33); ZHP02214647 (Pls.' ZHP Ex. 34); ZHP00359796 (Pls.' ZHP Ex. 35); ZHP00405021 (Pls.' ZHP Ex. 36)). That evidence is directly relevant, showing how the contamination was discovered and why it was disclosed, and also providing a solid comparator against which to evaluate Teva and Torrent's utter failure to adequately evaluate the API.

CONCLUSION

For the foregoing reasons, the Court should deny Defendants' motions in limine.

Dated: February 26, 2024

Respectfully submitted,

/s/ Ruben Honik
Ruben Honik
HONIK LLC
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Phone: (267) 435-1300
ruben@honiklaw.com

/s/ Daniel Nigh
Daniel Nigh
Nigh Goldenberg Raso & Vaughn, PLLC
14 Ridge Square NW
Third Floor
Washington, D.C. 20016
Phone: (850) 600-8090
dnigh@nighgoldenberg.com

/s/ Adam Slater
Adam Slater
MAZIE, SLATER, KATZ & FREEMAN, LLC
103 Eisenhower Pkwy, 2nd Flr.
Roseland, NJ 07068
Phone: (973) 228-9898
aslater@mazieslater.com

/s/ Conlee S. Whiteley
Conlee S. Whiteley
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, LA 70130
Phone: (504)-524-5777
c.whiteley@kanner-law.com

MDL Plaintiffs' Co-Lead Counsel

/s/ *Jorge Mestre*
Jorge Mestre
RIVERO MESTRE LLP
2525 Ponce de Leon Blvd., Suite 1000
Miami, FL 33134
Phone (305) 445-2500
jmestre@riveromestre.com

/s/ *Gregory P. Hansel*
Gregory P. Hansel
PRETI, FLAHERTY, BELIVEAU & PACHIOS, CHARTERED, LLP
One City Center
P.O. Box 9546
Portland, ME 04112
Phone: (207) 791-3000
ghansel@preti.com

Third-Party Payor Economic Loss Co-Lead Class Counsel